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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,425	12/03/2001	Paul L. Bartel	2318-386	6042

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,425	BARTEL ET AL.	
	Examiner	Art Unit	
	Hong Sang	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Bartel et al

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-7, drawn to an isolated polypeptide, classified in class 530, subclass 350.

   II. Claims 8-17, drawn to an isolated protein complex, classified in class 530, subclass 402, for example.

   III. Claims 18-21, drawn to a method for detecting an alteration in MMSC1 comprising analyzing a MMSC1 gene expression product, classified in class 435, subclass 6.

   IV. Claims 22, 30, drawn to a method for detecting an alteration in MMAC1 protein and a method for determining whether a mutation in a protein to which MMSC1 binds is predispositive for cancer, classified in class 435, subclass 7.1.

   V. Claim 23, drawn to a method of supplying a wild-type MMSC1 gene function or a MMSC1 function to a cell, classified in class 435, subclass 455.

   VI. Claims 24-29, 31, drawn to a method for diagnosing a predisposition for cancer comprising assaying the binding ability of MMSC1 or a fragment of MMSC1 to a wild type protein, a method of determining whether a

mutation in MMSC1 is predispositive for cancer, classified in class 435, subclass 7.1

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are patentably distinct because the products claimed in each group are different. For example, the product in Invention 1 is an isolated MMSC1 polypeptide or its mutants, the product in Invention 2 is an isolated protein complex comprising another protein MMAC1 or MMAC1 fragments or MMAC1 mutants, in addition to MMSC1 or MMSC1 fragments or MMSC1 mutants. These products have different properties such as binding activity; and different functions such as the function they play in cancer development and also have different structures. For these reasons, the Invention I and II are patentably distinct.

Furthermore, searching the inventions I and II together would impose a serious search burden. In the instant case, the Inventions I and II have a separate status in the art as shown by their different classifications. A polypeptide and a protein complex require different searches. An amino acid sequence search for SEQ ID NO 2 and 3 is required for the Invention I. However, Invention II compasses molecules such as MMSC1 fragments, MMAC1, MMAC1 fragments and MMAC1 mutants which are not required for the search of Invention I. As such, it would burdensome to search the Inventions I and II together.

Inventions I and III-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product polypeptide can be used to generate antibodies as opposed to its use in a method of diagnosing cancer or detecting mutation.

Searching the Inventions I and III-VI together would impose serious search burden. The Inventions I and III-VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the methods of detecting mutants or diagnosing cancer are not coextensive. Invention III-VI encompasses molecules and methods which are claimed in terms of MMSC1 gene expression product (Invention III), immunoassays (Invention III), biochemical activity inhibition (Invention III), testing binding interactions (Invention III-IV, VI), supplying a gene function to a cell (Invention V), MMAC1 mutants (Invention IV), antibody for MMSC1 (VI), which are not required for the search of Invention I. Furthermore, the search for Invention III-VI would require a text search for the method of detecting mutant or diagnosing cancer in addition to the polypeptides. Moreover, even if the polypeptide product was known, the method of using it to diagnose cancer or to detect mutants may be novel and unobvious in view of the preamble or active steps.

Inventions II and III-IV, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein complex can be used to catalyze an enzymatic reaction as opposed to its use in a method of detecting mutants or diagnosing cancer.

Searching the Invention II and III-IV, VI together would impose serious search burden. The inventions of Inventions II and III-IV, VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the protein complex and the methods of detecting mutants or diagnosing cancer are not coextensive. Invention III-IV, VI encompasses molecules and methods which are claimed in terms of immunoassays (Invention III), biochemical activity inhibition (Invention III), testing binding interactions (Invention III-IV, VI), antibody for MMSC1 (VI), which are not required for the search of Invention II. Furthermore, the search for Invention III-IV, VI would require a text search for the method of detecting mutants or diagnosing cancer in addition to the protein complex. Moreover, even if the protein complex was known, the method of using it to diagnose cancer or to detect mutants may be novel and unobvious in view of the preamble or active steps.

Inventions II and V are unrelated because the product of Invention II is not used or otherwise involved in the process of Invention V.

Inventions III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of detecting an alteration in MMSC1 (III), the method for detecting an alteration in MMAC1 (IV), the method of supplying a wild-type MMSC1 gene function or a MMSC1 function to a cell (V), and a method of diagnosing a predisposition for cancer (VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for the method of detecting an alteration in MMSC1, the method of detecting an alteration in MMAC1, the method of supplying a wild-type MMSC1 gene function or a MMSC1 function to a cell, and a method of diagnosing a predisposition for cancer differ significantly for each of the materials. For detecting an alteration in MMSC1 (Invention III), a MMSC1 gene expression product is used; the methodology such as immunoassays, and protein biochemical activity measurement is used in addition to measuring protein-binding interaction. For detecting an alteration in MMAC1 (Invention IV), an MMAC1 polypeptide is used. For supplying a wild-type MMSC1 gene function or a MMSC1 function to a cell (Invention V), a molecule which suppresses the transformed state of the cell was used. For diagnosing a predisposition for cancer (Invention VI), the formation of protein complex is

detected and antibody is used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions III-VI are patentably distinct.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**

otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chrisp HK for:

Hong Sang
Art Unit 1642
May 18, 2005